GEM® STAT

OPERATOR'S MANUAL

Mallinckrodt

SENSOR SYSTEMS, INC.

GEM®-STAT

Operator's Manual

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Product Description 1

A. INTENDED USE

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER LICENSED PRACTITIONER.

WARNING:
THE GEM-STAT SYSTEM CONSISTS OF SEVERAL NON-INTERCHANGEABLE COMPONENTS. USE COMPONENTS MANUFACTURED ONLY BY MALLINCKRODT SENSOR SYSTEMS. READ THE INSTRUCTIONS FOR USE PROVIDED WITH EACH COMPONENT BEFORE OPERATING THIS SYSTEM.

The GEM-STAT patientside Blood Chemistry Analyzer, when used in conjunction with the GEM-STATPAK, is used to measure blood gases, electrolytes and hematocrit of critically ill patients.

Because of its self-contained and automated design, the GEM-STAT is simple to operate. Simple operation allows blood samples to be analyzed at the patient bedside, thereby significantly reducing the total turnaround time of a blood chemistry measurement.

The GEM-STAT incorporates automatic calibration and includes end-user quality control solutions so that the system accuracy can be verified by the system operator at any time.

B. PRINCIPLES OF OPERATION

The purpose of the GEM-STAT System is to provide the operator with fast, accurate results, with a minimum amount of user preparation and maintenance.

No extraneous equipment or reagents are required for calibration, since all of the electrodes and calibrating solutions are contained within the disposable STATPAK cartridge. Set-up consists of inserting the STATPAK cartridge into the GEM-STAT instrument, which initiates a completely automated warm-up. During warm-up, the system performs a 2-point calibration and numerous self-checks to verify that it is operating properly.

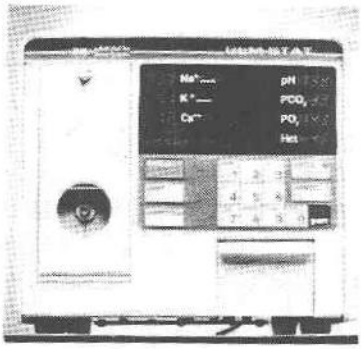
Accuracy is maintained throughout the life of the cartridge via one- and two-point calibrations that have been pre-programmed to occur automatically at fixed time intervals. Any time during operation, accuracy can be verified by the operator via the use of independent quality control solutions.

In many blood gas/electrolyte analyzers, the electrode membranes, solutions, pumps, and valves must be regularly checked and maintained by the user in order to insure consistent performance. With the GEM-STAT System, all of these components are within the disposable GEM-STATPAK. The instrument automatically rejects the cartridge when its sample capacity or total operating life is exceeded, which is long before any of the individual cartridge components would show degraded performance due to use. Biohazard has been minimized by a sealed waste bag that automatically collects used blood and flush solutions throughout the life of the STATPAK cartridge.

C. SYSTEM COMPONENTS AND FEATURES

GEM-STAT (Prod. No. 4300)

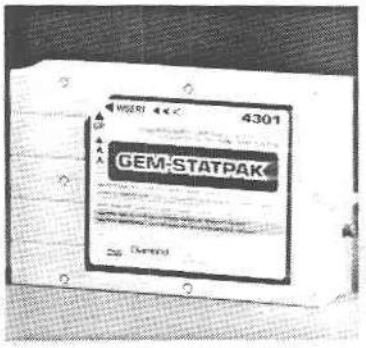
Electronic instrument for analyzing blood gases, electrolytes, and hematocrit.



- Measures PO_2, PCO_2, pH, K^+, Na^+, iCa^{++} and Hct.
- Derives Base Excess, HCO_3^- TCO_2, and O_2 SAT.
- Hard copy printout automatically provided with each analysis assures complete sample identification.
- Front Panel Display provides numeric readout for each measured analyte.
- Alphanumeric Display provides instrument status information, keyboard prompts, and additional parameter displays.
- Keyboard allows command and data entry.
- Temperature Correction capability via entry of patient temperature.

GEM-STATPAK (Prod. No. 4301)

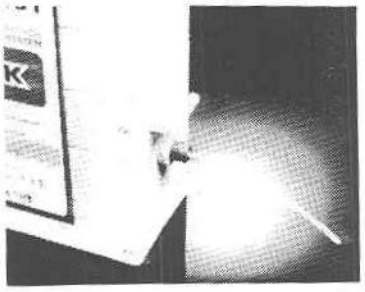
Disposable cartridge containing electrochemical sensors, calibrating and flush solutions, and waste container.

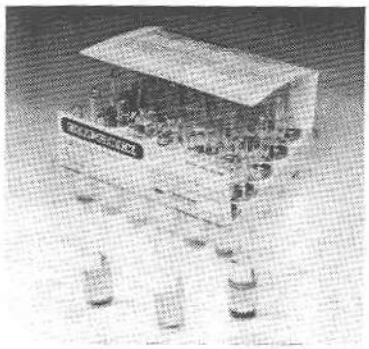


- Disposable
- Provides up to 50 tests or 24 hours of sampling capability.
- Self-contained cartridge includes sensors, calibration and flush solutions, and waste container.
- 48 hour standby period extends total cartridge use life to 72 hours.

GEM-SAMPLER (Prod. No. 4305)

Disposable attachment that allows introduction of blood samples to the GEM-STATPAK cartridge.

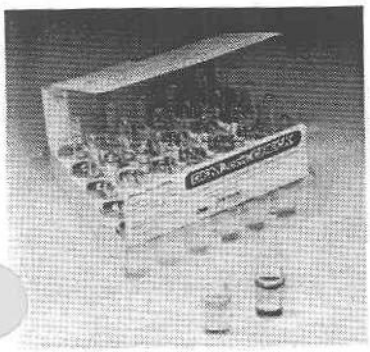




GEM-CHECK (Prod. No. 2306)

Aqueous solutions containing known values of gases and electrolytes that permit system quality control checks of pH, PO_2, PCO_2, K^+, iCa^{++}, and Na^+.

- Low, Normal, and High values provided in each package.
- Allows user to comply with laboratory QC requirements.



GEM-CRIT CHECK (Prod. No. 2309)

Aqueous solutions simulating known values of hematocrit that permit system quality control checks of Hct.

- Low and Normal values provided in each package.
- Allows user to comply with laboratory QC requirements.

D. SPECIFICATIONS

CAUTION

WHILE MALLINCKRODT SENSOR SYSTEMS WARRANTS THE GEM-STAT SYSTEM TO PERFORM WITHIN THE SPECIFICATION LIMITS STATED IN THIS MANUAL, IT IS THE RESPONSIBILITY OF THE USER TO REVIEW THE SPECIFICATIONS AND DETERMINE THE SUITABILITY OF THE SYSTEM FOR ANY PARTICULAR APPLICATION.

1. PARAMETERS

MEASURED PARAMETERS	RANGE	RESOLUTION
PO_2	0 TO 400 mmHg	1 mmHg
pH	6.80 TO 7.80	.01
PCO_2	5 to 99 mmHg	1 mmHg
Na^+	100 to 200 mM/L	.1 mM/L
K^+	0.1 to 9.9 mM/L	.1 mM/L
iCa^{++}	0.1 to 5.0 mM/L	.1 mM/L on display .01 mM/L on printout
Hct	5 to 60%	1%

DERIVED PARAMETERS	RANGE	RESOLUTION
HCO_3^-	3.0 to 60 mM/L	.1mM/L
TCO_2	3.0 to 60 mM/L	.1 mM/L
Base Excess	-30 to +30 mM/L	.1mM/L
O_2 SAT	30 to 99%	1%

2. PHYSICAL SPECIFICATIONS IN INCHES [CM]

	WIDTH	DEPTH	HEIGHT	WEIGHT
GEM-STAT	9.12 [23.2]	18.25 [46.4]	8.38 [21.3]	27.7 lb. (12.6 kg.)
GEM-STATPAK	2.00 [5.1]	8.06 [20.5]	5.00 [12.7]	25 oz. (.7 kg.)

3. QUALITY CONTROL SOLUTIONS

GEM-CHECK — 3 levels per package, 10 ampules each level. Each ampule contains 3 ml of solution pre-analyzed for pH, PO_2, PCO_2, K^+, Na^+, and iCa^{++}.

Low Level: Lower than normal blood values
Normal Level: Normal blood values
High Level: Higher than normal blood values

GEM-crit CHECK — 2 levels per package, 15 ampules each level. Each ampule contains 3 ml of solution pre-analyzed for Hct.

Low Level: Lower than normal blood values
Normal Level: Normal blood values

4. ADDITIONAL SPECIFICATIONS

Sample Volume	0.5 ml
Sampling Rate	Maximum 11 samples/hour
Response Time	110 seconds from sample introduction
Measurement Methodology	PO_2—Polarographic pH, Na^+, K^+, iCa^{++}, PCO_2—Potentiometric Hct—Conductivity
Calibration Method	Two-point calibration every 60 minutes. One-point calibration between samples.
Temperature Control	Electrode chamber maintained at 37°C, ±0.2°C.
Time and Date	Internal 24 hour calendar clock, battery powered.
Power Requirements	Domestic Version: 120 VAC +10% / -15% 60 Hz, 100 Watts. Export Version: will vary, refer to back panel of instrument.
Product Safety	UL Listed under UL-544*. Designed to comply with IEC 601.
Data Output Port	RS 232
Sample type	Whole blood with addition of approximately 25 USP units/ml Na Heparin or Li Heparin.

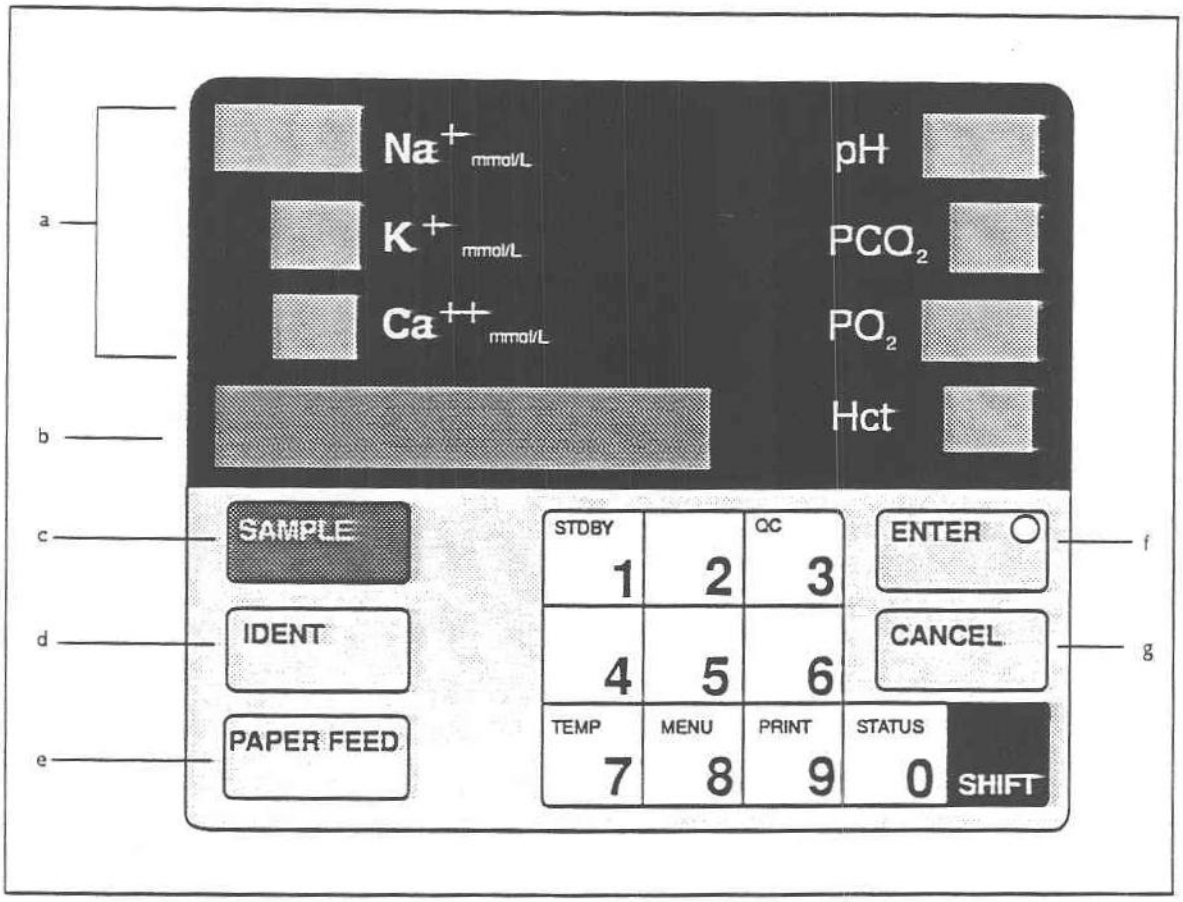
* Domestic version only

Controls, Displays, & Printouts

II

A. INSTRUMENT DISPLAYS & KEYPAD FUNCTIONS

(Fig. 1.) FRONT PANEL CONTROL AND DISPLAYS



1. FRONT PANEL DISPLAYS AND KEYPADS

DISPLAYS/KEYPADS	PG. REF.	FUNCTIONS
a. Numeric Window Displays; Na^+, K^+, iCa^{++}, Hct pH, PCO_2, PO_2	9	Displays parameter values for last blood sample analyzed.

DISPLAYS/KEYPADS	PG. REF.	FUNCTIONS
b. Alphanumeric Window Display	9	Shows system status (READY, RINSE, STANDBY, etc.), and user–supplied data (Identification nos., etc).
c. Sample Keypad	26	Press to aspirate blood sample.
d. Identification Keypad	26	Press prior to entering ID numbers.
e. Paper feed Keypad	17	Press to feed paper (used when changing paper).
f. Enter Keypad	9	Used to store values entered on numerical keypad, such as patient or operator ID, temperature, etc.
g. Cancel Keypad	9	Press to abort current function and return to previous mode.
h. Numeric Keypads	26	Used to enter numeric data, such as ID numbers.

Secondary Keypad Functions

By pressing SHIFT, and then the appropriate numeric keypad, the function printed on the keypad, defined as follows, will occur:

i. 1/STBY (Standby)	31	Press to initiate Standby mode.
j. 3/QC (Quality Control)	21	Press to initiate QC Test procedure.
k. 7/Temp (Temperature)	30	Press to temperature correct a previously analyzed sample.
l. 8/Menu	33-36	Press to select option(s) from menu.
m. 9/Print	31	Press to obtain duplicate printout of most recently analyzed blood sample.
n. 0/Status	31	Press to initiate printout that provides information regarding GEM-STATPAK cartridge life.

2. REAR PANEL CONTROL

Controls power to instrument and functions as circuit breaker. (Fig. 2)

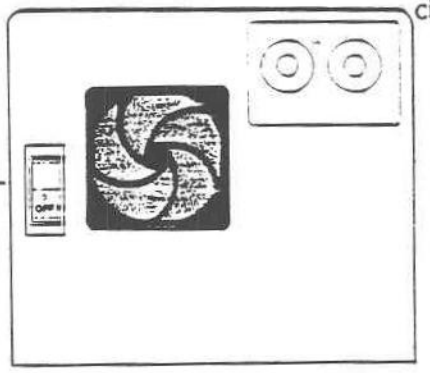


Fig. 2.

B. DISPLAY MESSAGES

DISPLAY MESSAGES	PG. REF.	DESCRIPTION
BAD DATE:	18	Invalid date has been entered. Try again.
BAD LOT NUM!	22	Invalid lot number has been entered. Try again.
BAD TIME	18	Invalid time has been entered. Try again.
CANCELLING	10	Current function is being aborted.
CRC FAILED	43	Indicates hardware fail; turn OFF, then ON. Try again. Contact customer service if problem continues.
DATE/TIME?	18	Accessed through MENU keypad WHEN CARTRIDGE IS NOT INSERTED. Press ENTER to view or set date and/or time, or CANCEL to return to previous mode of operation.
EXITING STBY	32	Occurs whenever exiting STANDBY (after pressing the SHIFT, then 1/STBY keypad while system is in STANDBY).
GOING 2 STBY	32	Indicates that the instrument is going to enter the STANDBY mode (after pressing the SHIFT then 1/STBY keypad while system is in READY).
HTR BLK FAIL	43	Instrument heater block has failed to maintain correct operating temperature. Contact Service Department.
INSERT CART	19	Instrument is ready to accept cartridge.
LN 000000000	22	A prompt asking that the lot number of Quality Control Solution be entered (after pressing SHIFT, then QC keypad).
MUST DO QC	22	QC has not been run on cartridge. At least 1 QC check must be run prior to analyzing the first blood sample on a new cartridge.
NO GOOD DATA	44	Data is unavailable to complete a requested calculation.
OP 000000000	26	Operator ID Number. "0's" appear if an operator ID number has not previously been entered, otherwise 0's will be replaced by previously entered ID numbers.
PA 000000000	26	Patient ID number. "0's" appear if a patient ID number has not previously been entered, otherwise 0's will be replaced by previously entered Patient ID numbers.
PLEASE WAIT	44	A request has been made that cannot be initiated because the instrument is "busy" performing another task.
PRINT ALL	34	Instrument is duplicating all QC and patient samples via request from user.

DISPLAY MESSAGES	PG. REF.	DESCRIPTION
PRINT ALL QC	34	Instrument is duplicating all QC print outs via request from user.
PRINT ALL?	34	Accessed through MENU keypad. Asking operator if all QC and patient sample printouts should be duplicated. Press ENTER to print, CANCEL to abort, or 8/MENU to continue to next request.
PRINT Q-C?	34	Accessed through MENU keypad. Asking operator if all QC print-outs should be duplicated. Press ENTER to print, CANCEL to abort, or 8/MENU to continue to next request.
PROCESS 1:49	27	Follows SAMPLING; countdown indicates time remaining to complete sample processing.
QC READY	22	Quality Control Lot Number has been entered and QC solution is ready to be analyzed.
R YOU SURE?	36	Appears following operator request to remove cartridge. Press CANCEL to abort or ENTER to open door. CARTRIDGE CAN NOT BE REINSERTED IF ENTER IS PRESSED.
READY 37.0 C	25	The instrument is ready to accept samples, and any other commands. Samples are analyzed at 37.0° C unless manually corrected to patient temperature.
RECOVERING	37	Instrument is recovering from a power failure. Heater block will take up to 4-1/2 minutes to readjust to correct temperature. Followed by RINSE M:SS.
REMOVE CART	36	Cartridge has been used to full capacity (the 24 hour use life or the 50 sample capacity has been reached), or, power was disconnected for more than 30 minutes. No more sampling can occur.
REMOVE CART?	36	Accessed through MENU keypad. Asking operator if door should be unlocked to provide access to cartridge. Press ENTER to unlock door, or CANCEL to return to previous mode.
REMOVE SAMPLE		User pressed CANCEL during "SAMPLING."
RINSE M:SS	27	Always occurs following SAMPLE PROCESSING, STANDBY, RECOVERING, and DATA RETRIEVAL. The count down indicates the amount of time remaining in the rinse cycle.
SAMP CANCEL	15	User pressed CANCEL during "PROCESSING."
SAMPLING	27	System is aspirating a sample.
*SELF TEST	25	Occurs immediately following GEM-STAT power ON and lasts for about 10 seconds.

DISPLAY MESSAGES	PG. REF.	DESCRIPTION
STANDBY	32	Instrument is in the STANDBY mode. No programming or sampling can take place.
*T=XX.X C.	30	Prompt asking for a temperature input so temperature correction can be performed. Occurs after pressing 7/TEMP.
2 PT CAL M:SS	25	Instrument is performing a 2-point calibration. The countdown indicates the amount of time remaining in the calibration. Occurs 20 minutes following WARMUP and once per hour thereafter.
2 PT. CAL.?	33	Accessed through MENU keypad. Asking operator if a two–point calibration should be initiated. Press ENTER to perform two-point calibration, CANCEL to abort, or 8/MENU to continue to next request.
VALVE FAILED	44	Indicates an internal problem with the instrument. May be corrected by turning the instrument OFF, then ON again. If message does not disappear, call the Service Department.
WARMUP 43:00	25	Indicates that the system is preparing for sampling and performing internal calibrations. Countdown indicates time to complete warmup.
3/22/89	18	Date to which instrument is set; appears only after the SHIFT and 8/MENU keypads have been pressed during INSERT CART mode.
14:22:33	18	Time to which instrument is set; always appears in military, or 24-hour, format.

C. PRINTOUTS

The following are examples of the GEM-STAT printouts.

1. PATIENT SAMPLE PRINTOUT

Sample Number (Sequentially numbered)

Time Sample was analyzed

Date Sample was analyzed

Patient Identification Number

Operator Identification Number

Temperature at which values are reported

Blood Values

```
*GEM-STAT*

SAMPLE NUMBER          2
TIME:     03:52 PM
DATE:     08/23/89
PAT.   ID:  123456789
OPER.  ID:  987654321
TEMP:          37.0 °C
--------------------
 pH          7.35
 PCO2        38     mmHg
 PO2         105    mmHg
 HCO3        21.2   mmol/L
 TCO2        22.4   mmol/L
 BE          - 3.3  mmol/L
 SAT         97.8   %
--------------------
 Hct         48     %
 Na+         139.5  mmol/L
 K+          4.1    mmol/L
 Ca++        1.21mmol/L
```

Fig. 3

2. QUALITY CONTROL PRINTOUT

Sample Number (Sequentially numbered)

Indicates that sample is a Quality Control Sample (not a blood sample).

Time QC solution is analyzed

Date QC solution is analyzed

Operator Identification Number

Lot Number corresponding to QC Ampule

Level of QC test solution

QC Test Values

```
*GEM-STAT*

SAMPLE NUMBER          4
QUAL. CONTROL CHECK
TIME:     04:04 PM
DATE:     08/23/89
OPER.  ID: 987654321
LOT NUM:          1009
LOW LEVEL SAMPLE
 pH          7.01
 PCO2        77     mmHg
 PO2         80     mmHg
 Na+         129.4  mmol/L
 K+          2.5    mmol/L
 Ca++        .91mmol/L
```

Fig. 4

3. CARTRIDGE STATUS PRINTOUT

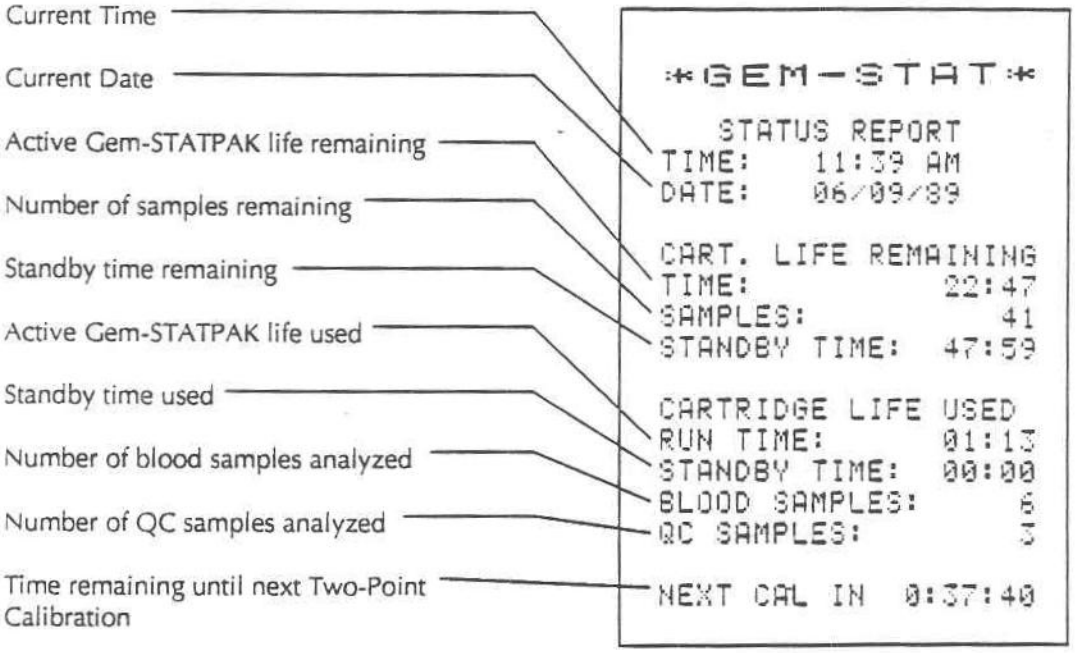


Fig. 5

4. SAMPLE CANCELLED PRINTOUT

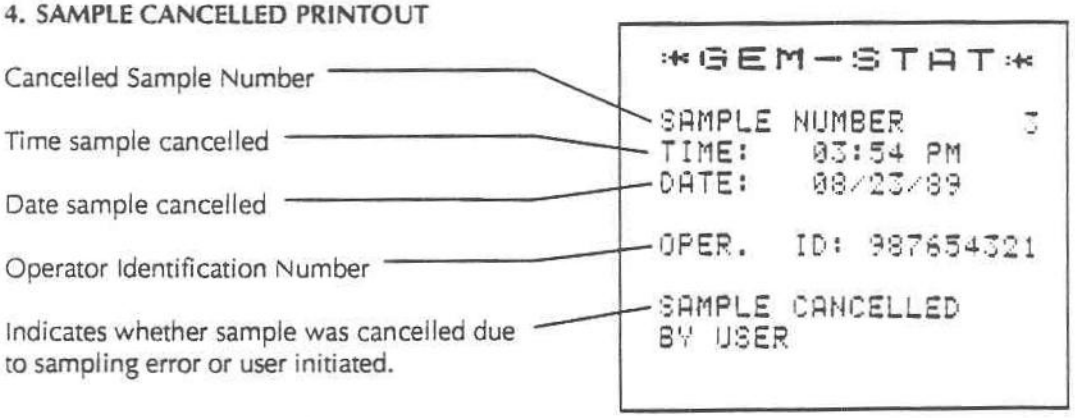


Fig. 6

5. CARTRIDGE STATUS SHOWING CALIBRATION FAILURE PRINTOUT

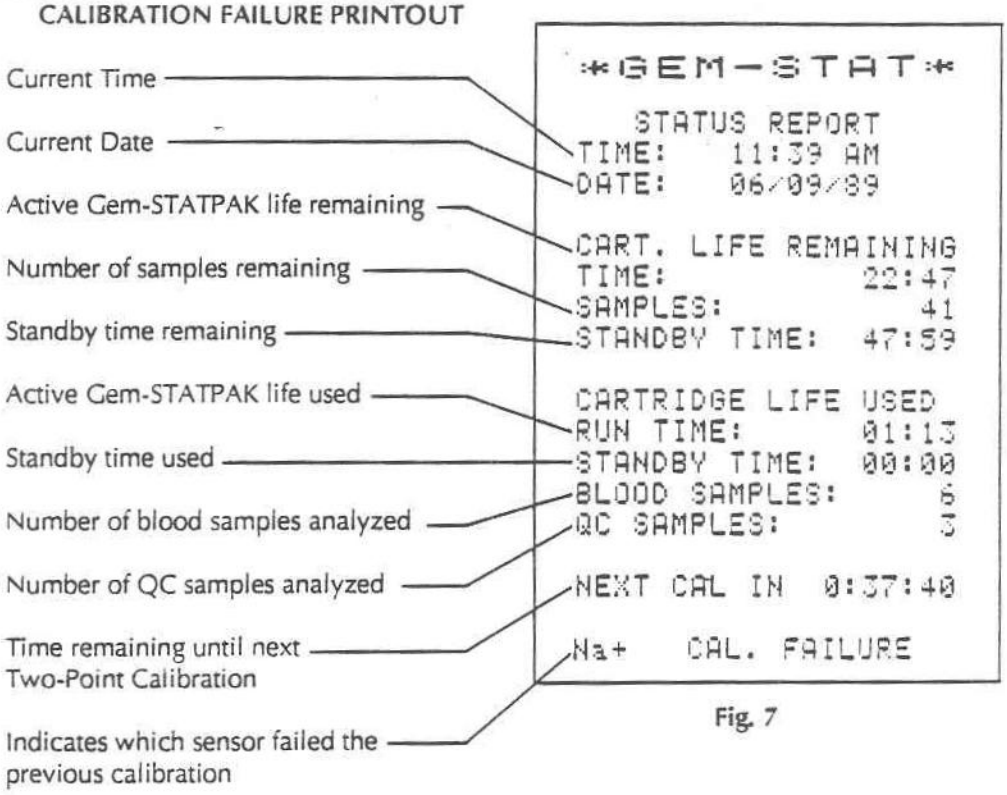


Fig. 7

6. COMPLETION OF SUCCESSFUL CALIBRATION PRINTOUT

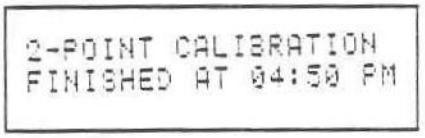


Fig. 8

7. CALIBRATION FAILURE PRINTOUT

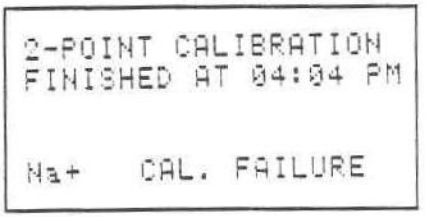


Fig. 9

Installation & Preparation III

A. INSPECTION OF COMPONENTS

Inspect each of the individual components for external signs of damage. The GEM-STATPAK cartridge and packaging should not exhibit any signs of moisture. All other components must be clean and undamaged. If any component appears defective, contact a Mallinckrodt Sensor Systems representative. Refer to Section VI D, Service & Returned Goods Policy, page 45.

CAUTION

UNDER NO CIRCUMSTANCES SHOULD THE COVER OF THIS INSTRUMENT BE REMOVED. THERE ARE NO USER SERVICEABLE PARTS IN THE INSTRUMENT.

B. SYSTEM INSTALLATION

Install the GEM-STAT by placing it in any convenient location. Attach the line cord to any grounded, properly wired outlet that meets the voltage rating stamped on the back panel of the instrument.

WARNING

IN ORDER TO PREVENT ELECTRICAL SHOCK HAZARD TO OPERATOR, THIS DEVICE MUST BE CONNECTED TO A PROPERLY WIRED GROUNDED RECEPTACLE.

C. INSTALLING PRINTER PAPER

WHEN A RED STRIPE APPEARS ON THE EDGE OF THE PAPER, THERE ARE APPROXIMATELY 2 FEET OF PAPER REMAINING, OR ENOUGH FOR 5-6 SAMPLE ANALYSES.

Open printer doors located on the sides and the front of the GEM-STAT (Fig. 10, A).

Remove any remaining printer paper and cardboard spool from spindle.

With paper coming over the top of the roll, slide new paper roll onto spindle until roll "seats" (just past retaining ring).

Thread paper through printer as shown in Fig. 10, B.

Press PAPER FEED keypad located on front panel to automatically complete the paper thread, as shown in Fig. 10, C.

Close both printer doors.

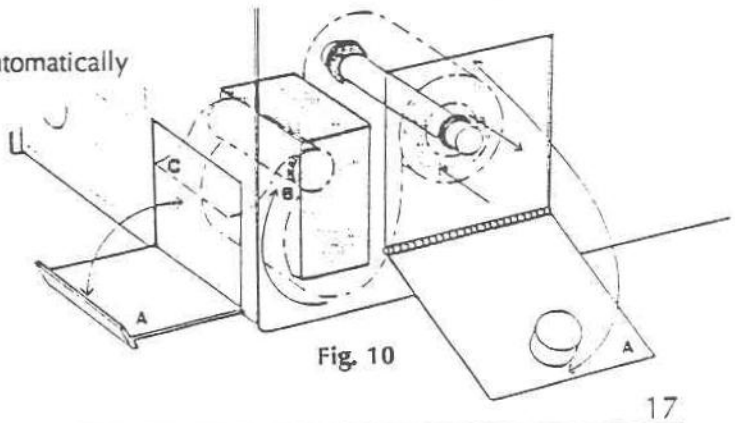
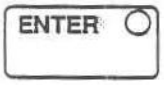
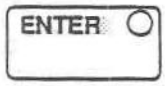
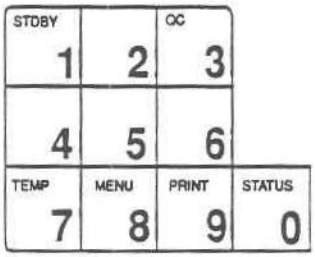
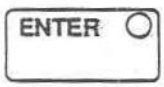
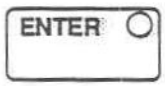
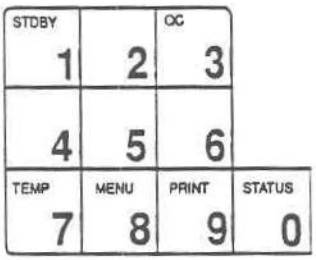
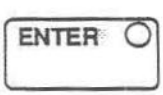


Fig. 10

D. SETTING THE DATE AND TIME

Date and time can only be set when there is no cartridge in the instrument and the display reads "INSERT CART".

The date and time have been initially set by Mallinckrodt Sensor Systems, Inc. If the date and/or time need to be re-set, proceed as follows:

ACTION	RESULT
 1. Press SHIFT keypad, then 8/MENU keypad. (You may have to press the 8/MENU keypad twice).	Alphanumeric display will read "DATE/TIME?", and ENTER keypad will be flashing.
 2. Press ENTER keypad.	Alphanumeric display will read the currently set date and ENTER keypad will be flashing.
 3a. If displayed date is correct press ENTER.	Display will read the currently set time and ENTER keypad will be flashing. If time is correct, proceed to step 5a. If time needs correction, proceed to step 5b.
OR	
 3b. If displayed date is incorrect, use numeric keypads to enter 6 digits that signify the appropriate date. (2 each for the month, day, and year)	Alphanumeric display will show the entered digits. ENTER keypad will be flashing.
 4. Press ENTER.	Alphanumeric display will read the currently set time and ENTER keypad will be flashing.
 5a. If displayed time is correct press ENTER.	Instrument will return to "INSERT CART", and will keep track of the date and time until it is changed. Proceed to the next section.
OR	
 5b. Use numeric keypad to enter 6 digits that signify the appropriate time (2 each for the hour, minute and second). "AM" and "PM" cannot be read by the instrument, therefore you MUST use military standard, e.g., 2:12:00 PM must be entered as 14:12:00.	Alphanumeric display will show the entered digits. ENTER keypad will be flashing.
 6. Press ENTER.	Instrument will return to its previous mode, and will keep track of the date and time until it is changed.

E. INSERTING THE GEM-STATPAK

NOTE: VERIFY THE DATE AND TIME PRIOR TO INSERTING GEM-STATPAK; SEE PAGE 18.

THE GEM-STATPAK MUST BE INSERTED INTO THE GEM-STAT AT LEAST 43 MINUTES PRIOR TO USE TO ALLOW FOR GEM-STATPAK WARM-UP/ CALIBRATION PERIOD.

1. Plug GEM-STAT line cord into a suitable power source.
2. Turn GEM-STAT instrument ON via rear power switch located on the BACK of the instrument. Display will read "Self Test" for 10 seconds, then will read "Insert Cart."
3. After verifying the expiration date printed on outer package, remove GEM-STATPAK from protective package. Make sure that the GEM-STATPAK and the packaging are completely dry; do not use if there are any signs of moisture.

CAUTION

IF THERE IS ANY MOISTURE INSIDE BAG OR ON CARTRIDGE, DO NOT USE CARTRIDGE. OPEN A FRESH GEM-STATPAK AND CALL CUSTOMER SERVICE.

4. Open the LARGE hinged door on the front of the instrument (Fig 11).

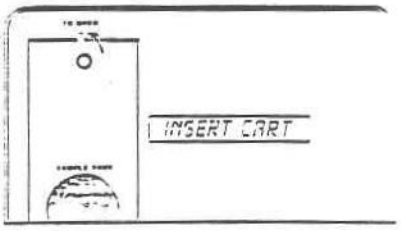


Fig. 11

CAUTION

THE INSTRUMENT DISPLAY MUST READ "INSERT CART" BEFORE INSERTING THE GEM-STATPAK CARTRIDGE.

5. Remove the protective cover and immediately insert the GEM-STATPAK into the cartridge compartment, aligning the GEM-STATPAK according to the labelling (Fig. 12).

CAUTION

CARTRIDGE MUST BE INSERTED INTO THE GEM-STAT INSTRUMENT WITHIN ONE MINUTE OF REMOVAL OF PROTECTIVE COVER.

DO NOT USE AFTER THE INDICATED EXPIRATION DATE.

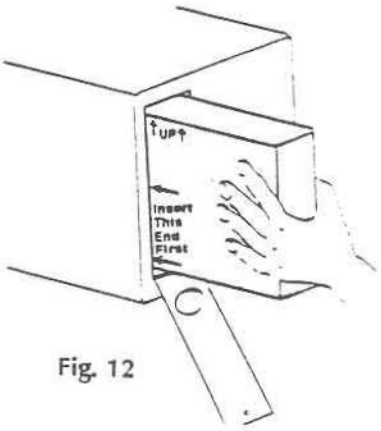


Fig. 12

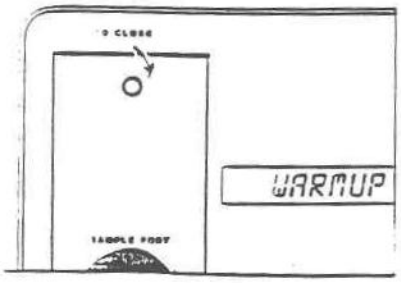


Fig. 13

6. Close the door securely. Knob will automatically set and **door will lock.** (Fig. 13) Display will read "WARM UP, MM:SS".

CAUTION

ONCE INSERTED, THE AUTOMATIC DOOR LOCK PREVENTS THE CARTRIDGE FROM BEING INADVERTENTLY OPENED. THE DOOR WILL UNLOCK ONLY AFTER THE USEFUL LIFE OF THE CARTRIDGE HAS BEEN EXCEEDED (50 SAMPLES OR 24 HOURS OF RUNNING TIME), OR A SPECIAL KEY SEQUENCE IF FOLLOWED (PAGE 36).

Calibration and Quality Control

IV

A. CALIBRATION

1. DESCRIPTION

The Gem-Stat System performs an automatic hourly two-point calibration. During this calibration, each sensor's performance will be checked internally to verify that the system is calibrating itself correctly. A Calibration Message will be printed (Fig. 14), following each successful two-point calibration.

```
2-POINT CALIBRATION
FINISHED AT 12:35 AM
```

Fig. 14

2. CALIBRATION FAILURE DETECTION

If the performance of one or more of the sensors is outside specified limits, all of the following will occur:

a. The Calibration Message will indicate the failed sensor (Fig. 15).

b. The failed sensor message will be printed on any subsequent status print-outs until the sensor falls into specification (which often happens with the next two-point calibration).

c. Any measurements made by the failed sensor will be "blanked out" on the corresponding window display. The analyte in question will have a "?" next to it on the patient printout.

```
2-POINT CALIBRATION
FINISHED AT 11:21 AM

Na+   CAL. FAILURE
```

Fig. 15

3. PROCEDURE FOR CORRECTING CALIBRATION FAILURE

If a calibration failure is indicated by the calibration print-out, initiate a two-point calibration using the procedure on pg. 33. If the two point-calibration failure persists, replace the GEM-STATPAK cartridge and call customer service.

Occasionally, a "?" may appear next to an analyte on the sample print-out even though the previous two-point calibration was successful. This usually results from a handling problem with the sample. Immediately request a Status print-out by pressing Shift, then 0/Status. If the Status indicates no problem with the previous calibration, simply retest a fresh sample.

B. QUALITY CONTROL

1. DESCRIPTION

Mallinckrodt Sensor Systems Quality Control Solutions (GEM-CHECK and GEM-crit CHECK) verify the performance specifications of the GEM-STAT and GEM-STATPAK components.

The solutions are adjusted at the factory to known concentrations of O_2, pH, PO_2, PCO_2, K^+, iCa^{++}, Na^+, and Hct. Multiple levels are included so that performance can be verified over a wide range.

The values obtained from analyzing the solution on the GEM-STAT are compared with the "Expected Values" on the printed insert thus verifying the performance of the system. FOR A COMPLETE DESCRIPTION OF "INTERPRETATION OF RESULTS," REFER TO THE PRODUCT INSERT PROVIDED WITH EACH QUALITY CONTROL PRODUCT.

The frequency of the system's verification is at user discretion and dictated by the user's own quality control program. Many federal and state regulatory requirements, however, dictate that all three levels of GEM-CHECK solutions be run each day. Because the hematocrit sensor is indicated for trending only, it is the user's discretion whether to quality control this parameter. Please determine the requirements governing your institution.

Mallinckrodt Sensor Systems Quality Assurance Manual (prod. no. 380023) contains descriptions, procedures, and data recording information for quality control checks performed on GEM-STAT.

WARNING

USE ONLY MSS QUALITY CONTROL SOLUTIONS. SOLUTIONS DESIGNED FOR USE WITH OTHER INSTRUMENTS WILL PRODUCE ERRONEOUS RESULTS AND MAY DAMAGE THE GEM-STATPAK SENSORS.

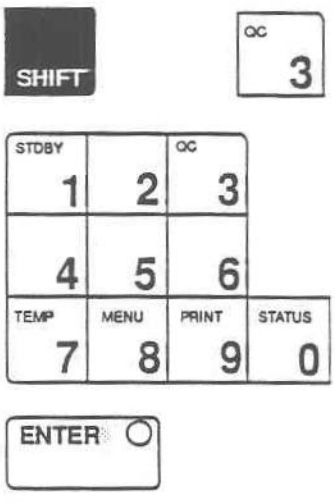
CAUTION

SEE PACKAGE INSERT PROVIDED WITH EACH QUALITY CONTROL PACKAGE AND SECTION VII, OPERATING INSTRUCTIONS, BEFORE ATTEMPTING TO USE THE QUALITY CONTROL SOLUTIONS.

2. PROCEDURE

System must be in the READY mode.

ACTION	RESULT
1. Press SHIFT keypad, then 3/QC keypad.	Alphanumeric display will read: "LN 000000000?" and ENTER keypad will be flashing.
2. Use numeric keypads and enter lot number that is printed on the label of each GEM-CHECK or GEM-crit CHECK ampule.	Alphanumeric display will show the entered digits and ENTER keypad will be flashing.
3. Press ENTER.	Alphanumeric display will read: "QC READY." QC must be processed within one minute of entering ID number or instrument will revert to READY mode.
4. Agitate ampule gently to mix and snap off at neck (Fig. 16).	
5. PRESS START to aspirate solution directly from glass ampule (Fig. 17).	



NOTE: THE PRINTOUT WILL NOT DISTINGUISH THE CONTROL SOLUTION FROM A PATIENT BLOOD SAMPLE UNLESS THIS SEQUENCE IS FOLLOWED, AND THE ALPHANUMERIC DISPLAY READS "QC READY."

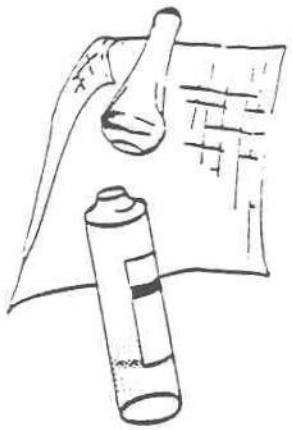


Fig. 16

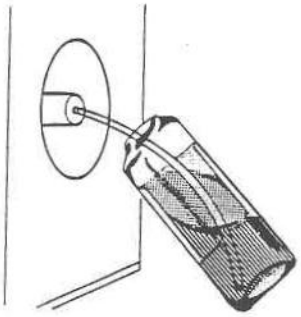


Fig. 17

```
*GEM-STAT*

SAMPLE NUMBER          4
QUAL. CONTROL CHECK
TIME:    04:04 PM
DATE:    08/23/89
OPER.  ID: 9876543321
LOT NUM:          1009
LOW LEVEL SAMPLE
 pH         7.01
 PCO2       77    mmHg
 PO2        80    mmHg
 Na+      129.4 mmol/L
 K+         2.5 mmol/L
 Ca++       .91mmol/L
```

Fig. 18 – Example of Low Level QC.

CAUTION:

IT IS RECOMMENDED THAT THE TOP PORTION OF THE AMPULE BE WRAPPED IN A 2 X 2 GAUZE PAD OR EQUIVALENT TO AVOID POSSIBLE SKIN PUNCTURE (FIG. 16).

CAUTION:

STABILITY OF QUALITY CONTROL SOLUTION DEGRADES QUICKLY AFTER OPENING GLASS AMPULE. PROCEED WITH SAMPLE ANALYSIS WITHIN 1 MINUTE AFTER OPENING AMPULE.

3. INTERPRETATION OF RESULTS

a. Compare instrument readings on printout with the "Expected Values" on the package insert provided with the quality control Solutions. Be sure to refer only to GEM-STAT values.

b. If instrument readings are outside the limits of any of the "Expected Ranges," immediately retest with freshly opened solutions, using the above protocol. IF RESULTS AGAIN ARE OUTSIDE OF THE "EXPECTED RANGE," INITIATE A 2 PT CAL ACCORDING TO THE INSTRUCTIONS ON PG. 33. IF RESULTS ARE STILL OUTSIDE OF RANGES REPLACE CARTRIDGE AND CONTACT CUSTOMER SERVICE.

Mallinckrodt Sensor Systems will replace or give credit for any cartridge that does not fall within the ranges printed on the insert provided with the GEM-CHECK and GEM-crit CHECK under the following conditions: (1) THE GEM-STATPAK CARTRIDGE HAS NOT BEEN USED FOR PATIENT ANALYSIS, (2) The "Do Not Use After" date has not been exceeded, and (3) All printouts showing the erroneous values are returned to MSS with the cartridge.

See pg. 45 for details concerning our Returned Goods Policy.

c. The derived parameters (BE, TCO_2, HCO_3, and O_2 SAT) are direct calculations of the measured parameters. If the GEM-CHECK or GEM-crit CHECK indicates that the following measured parameter is out of specification, the corresponding calculated parameter should be considered inaccurate:

MEASURED PARAMETER	DERIVED PARAMETER
PO_2	O_2 SAT
PCO_2	HCO_3, TCO_2, BE
pH	HCO_3, TCO_2, BE
K^+	NA
Na^+	NA
Ca^{++}	NA
Hct	O_2 SAT, BE

C. VALUE LIMIT CHECKING

Gem-Stat automatically checks high and low limits for all analyte results. If a measured or derived value is outside the specified limit, that analyte will be blanked on the display and print-out until its value returns to within the acceptable range. In addition, any derived parameters that are calculated from a measured value are blanked.

Operation V

A. SUMMARY OF OPERATION

After initial installation and after turning on the GEM-STAT, the following sequence of events will always occur. This is the basic framework of the GEM-STAT cycle (Fig. 19.) For specific programming functions that may occur during each cycle, see pg. 35.

ALPHANUMERIC DISPLAY MESSAGE	DESCRIPTION
SELF TEST/PLEASE WAIT	This is an internal instrument check which takes about 10 seconds.
INSERT CART	(Insert GEM-STATPAK cartridge.) This notifies the operator that a cartridge can be inserted in the GEM-STAT. Date and time should be set (if necessary) before inserting GEM-STATPAK.
WARMUP MM:SS	Following cartridge insertation, a 43 minute warmup takes place, during which time the system is calibrated. MM:SS denotes a countdown (minutes and seconds) of time remaining until the warmup is completed.
READY 37.0 C	System is ready to process samples. Instrument will analyze blood sample at 37.0°C.
2 PT CAL M:SS	(2 point calibration.) This occurs 20 minutes following completion of Warm Up and at 1 hour intervals thereafter. Total time for a 2 point calibration is 4 minutes, 30 seconds. M:SS denotes countdown (minutes and seconds) of time remaining to complete the calibration.

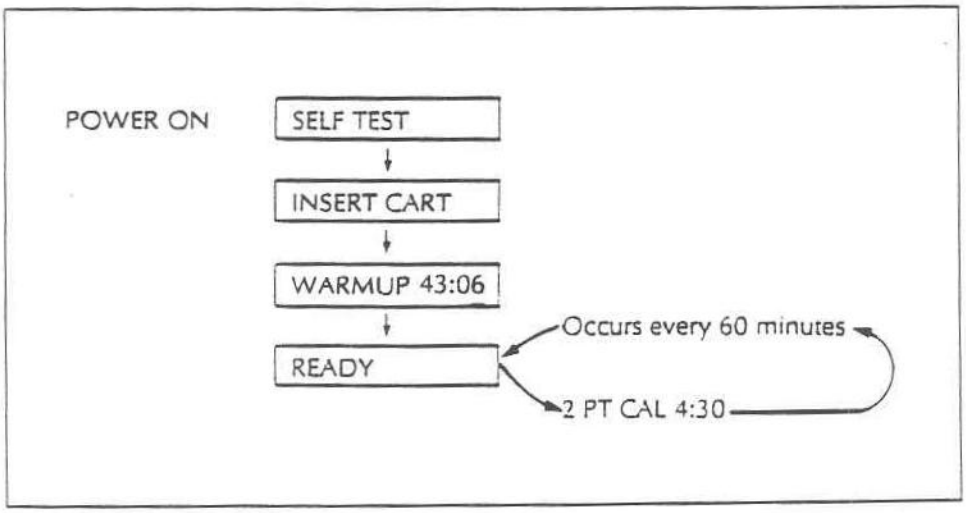


Fig. 19.

B. RUNNING A SAMPLE: STEP BY STEP PROCEDURE

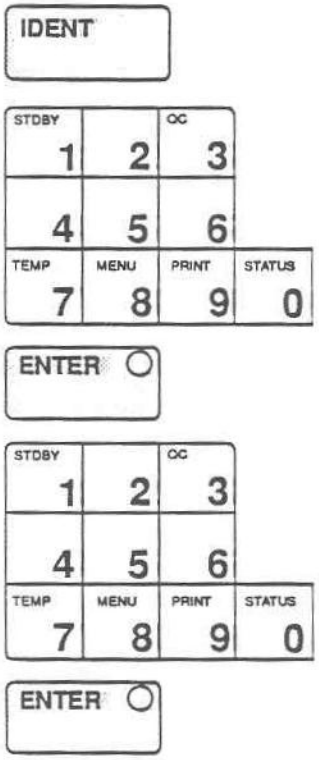
NOTE: FOR COMPLETE EXPLANATION OF KEYBOARD FUNCTIONS, SEE PG. 9.

1. COLLECTING THE BLOOD

To assure the highest accuracy possible of each analysis, follow these steps:

- Using a heparinized collection device (25 USP units/ml Na Heparin or Li Heparin), obtain 3/4 to 1 cc of blood from the patient.
- Minimize the introduction of air into the sample by "pushing" the dead air out of the syringe. Air contamination can change the gas values in the blood.
- Syringe should be inverted to mix heparin immediately after purging air. Sample should be mixed again immediately prior to analysis to avoid erroneous Hct.
- Store sample in ice if analysis cannot take place within 5 minutes of collection. Blood gas levels change rapidly.

2. ENTERING PATIENT AND OPERATOR IDENTIFICATION NUMBERS



ACTION	RESULT
a. Press IDENT.	Alphanumeric display will read: "PA000000000" and ENTER keypad will be flashing
b. Use numeric keypad to enter the Patient ID number, up to nine digits.	Alphanumeric display will show entered digits. If numbers are not correct, press "CANCEL" and begin again.
c. Press ENTER when the Patient ID number has been correctly entered.	Alphanumeric display will show "OP000000000" (If an Operator ID number has been entered previously, it will replace the "0's" in the display.) If Operator ID is correct, proceed to Step e.
d. Use numeric keypad to enter Operator ID number.	Alphanumeric display will show entered digits.
e. Press ENTER when Operator ID number has been correctly entered.	ENTER light will stop flashing and display will return to its previous mode.

Patient ID numbers must be entered before each blood sample.

3. ASPIRATING THE SAMPLE

WARNING

DO NOT INJECT SAMPLE DIRECTLY INTO SYSTEM VIA A SYRINGE. THIS WILL CAUSE SERIOUS DAMAGE TO BOTH THE CARTRIDGE AND THE INSTRUMENT. USE THE GEM-SAMPLER ACCORDING TO THE FOLLOWING INSTRUCTIONS:

a. Attach the GEM-SAMPLER to the inlet of the GEM-STATPAK by sliding the sampler into the inlet until the tubing is inserted as far as it will go, as indicated when the "STOP" line is flush with the opening (Fig. 20).

b. Insert the open end of the GEM-SAMPLER into a HEPARINIZED blood collection device.

c. Make sure that open end of the GEM-SAMPLER is immersed sufficiently in the blood sample such that 0.5 cc of blood can be aspirated (Fig. 21).

d. Press START SAMPLE. Alphanumeric display will read "SAMPLING" while blood is being aspirated.

   DO NOT remove sample until display changes to "PROCESS 1:50."

e. The system will cycle as shown in Fig. 22.

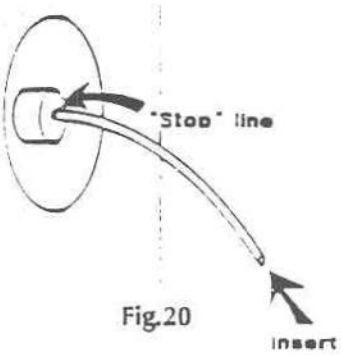


Fig.20

NOTE: FOR MAXIMUM PERFORMANCE IT IS RECOMMENDED THAT A NEW GEM-SAMPLER BE USED FOR EVERY SAMPLE ANALYZED.

CAUTION

IF AIR IS INADVERTENTLY INTRODUCED INTO SAMPLE DURING ASPIRATION, RESULTS WILL BE ERRONEOUS. SHOULD AIR BE ACCIDENTALLY ASPIRATED, PRESS "CANCEL" TO ABORT ANALYSIS.

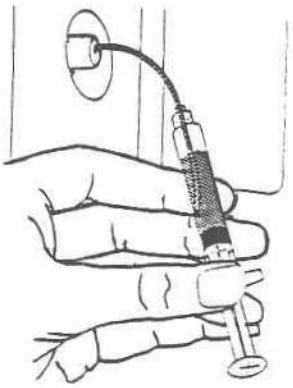


Fig.21

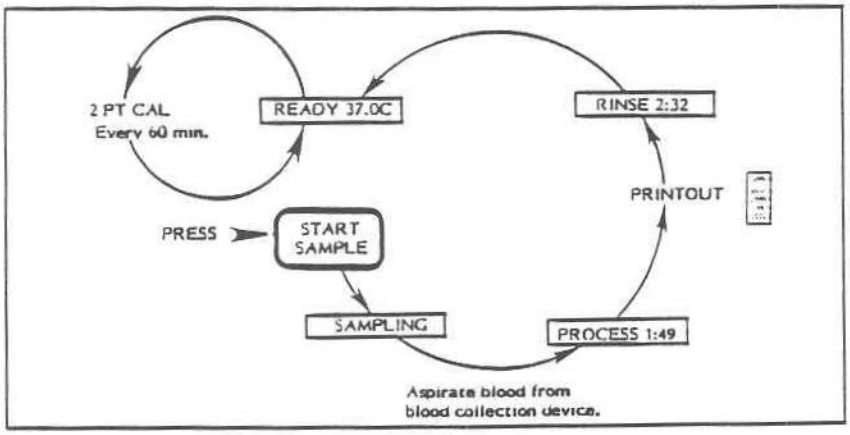


Fig.22

4. INTERPRETATION OF RESULTS

Following is an explanation of the information provided on a GEM-STAT patient printout (Fig. 23).

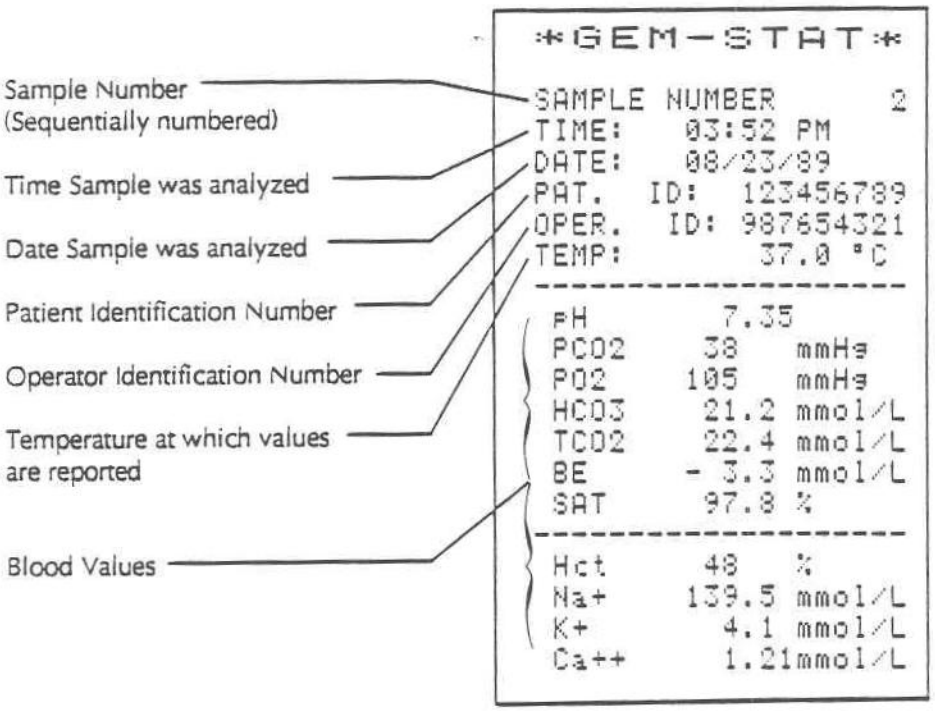


Fig. 23

The following table provides ranges of normal whole blood expected values for the parameters measured by the GEM-STAT. These ranges should only be considered as general guidelines. It is recommended that users initially run duplicate samples comparing the GEM-STAT with their clinical laboratory. Different instruments and laboratory techniques can produce differences in results, and each institution should determine the appropriate range of expected values for use with the GEM-STAT.

NORMAL EXPECTED VALUES FOR WHOLE BLOOD

PARAMETERS	ARTERIAL	VENOUS		REFERENCE
pH	7.38-7.44	7.36-7.41		(1)
PCO_2	35-40	40-45	mmHg	(1)
PO_2	95-100	*	mmHg	(1)
HCO_3^-	21-28	*	mM/L	(1)
TCO_2	19-24	*	mM/L	(1)
BE	-3.3 to +2.3	*		(1)
SAT	94-100	*	%	(1)
Hct	37-50	37-50	%	(2)
Na^+	136-142	136-142	mM/L	(1)
K^+	3.8-5.0	3.8-5.0	mM/L	(1)
Ca^{++}	1.0-1.3	*	mM/L	(1)

NOTE: VENOUS PARAMETERS MARKED WITH AN ASTERISK (*) CAN VARY SUBSTANTIALLY BETWEEN INDIVIDUALS AND VENIPUNCTURE SITES.

REFERENCES:

1. Davidsohn, I., and Henry, J.B.: Todd-Sanford Clinical Diagnosis by Laboratory Methods, W.B. Saunders Co., Philadelphia, 15th Edition, 1974.
2. Tietz, N.W., Fundamentals of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 1982.

CAUTION:

WITH PATIENTS HAVING SEVERELY ABNORMAL PLASMA OSMOLARITIES, THE HEMATOCRIT VALUES PRODUCED BY THE GEM-STAT MAY DIFFER SIGNIFICANTLY FROM THOSE PRODUCED BY A CELL COUNTER. IN GENERAL, ABNORMALLY HIGH PLASMA OSMOLARITY WILL CAUSE THE GEM-STAT HEMATOCRIT TO READ LOW RELATIVE TO A CELL COUNTER.

C. OTHER INSTRUMENT FUNCTIONS

1. TEMPERATURE CORRECTION

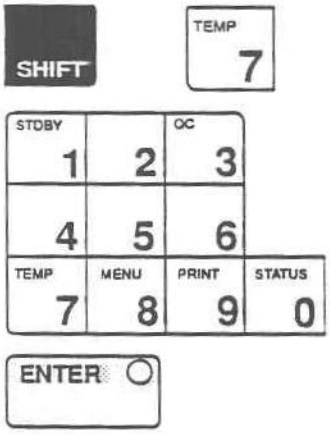
DESCRIPTION

The GEM-STAT System always analyzes the current blood sample at 37.0° C.

The operator may prefer to calculate blood gas values at the actual patient temperature (which may be different than 37.0°C). The GEM-STAT can recalculate a previously analyzed blood sample to the desired temperature.

Only the most recently analyzed blood sample can be temperature corrected.

PROCEDURE



ACTION	RESULT
1. Press the SHIFT, then 7/TEMP.	Display will read: "T = 37.0° C?" and ENTER keypad will be flashing.
2. Use numeric keypad to enter 3 digits that signify the appropriate temperature (to the nearest 0.1° C).	Alphanumeric display will show the entered digits. If numbers are not correct, press "CANCEL" and begin again.
3. Press ENTER.	A new printout will appear with blood values corrected to the entered temperature (Fig. 3, p. 14).

2. DUPLICATING PRINTOUT OF LAST SAMPLE ANALYSIS

PROCEDURE

ACTION	RESULT
Press SHIFT, then 9/PRINT keypad.	Previous print out will be duplicated.

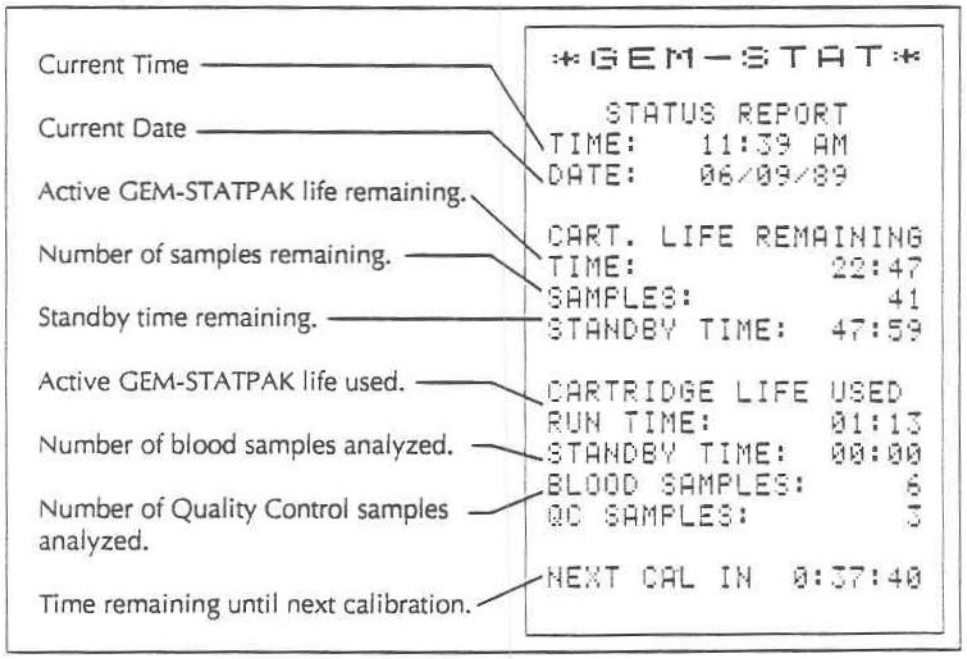
3. DETERMINING CARTRIDGE STATUS

Description

The Cartridge Status keypad informs the user upon demand several aspects pertaining to the status of the GEM-STATPAK disposable cartridge.

Procedure

ACTION	RESULT
Press SHIFT, then O/STATUS keypad.	Information printed as shown in Fig. 24.



(Fig. 24) STATUS REPORT

4. INITIATING STANDBY MODE

DESCRIPTION

The total 72-hour cartridge life is comprised of two phases: a 24-hour ACTIVE phase, and a 48-hour STANDBY phase.

The ACTIVE phase of the GEM-STATPAK refers to actual cartridge running time. During the active phase, calibrations occur once every hour. By interrupting the ACTIVE phase with STANDBY, calibration fluids in the cartridge are conserved, thereby extending the useful life of the cartridge for up to 72 hours. When the calibrating solutions have been depleted, the active phase (and useful life) of the cartridge is over.

The 24-hour ACTIVE life can be interrupted at any time, as often as desired, for up to 48 hours, allowing the cartridge to be used over a total period of 72 hours.

NOTE: SAMPLES CAN ONLY BE ANALYZED DURING THE ACTIVE PHASE.

TOTAL CARTRIDGE RUNNING TIME (ACTIVE) CANNOT EXCEED 24 HOURS. INSTRUMENT WILL AUTOMATICALLY DISPLAY "REMOVE CART" IF THE FULL 24 HOURS OF RUNNING TIME HAVE BEEN USED.

TOTAL CARTRIDGE STANDBY TIME CANNOT EXCEED 48 HOURS. INSTRUMENT WILL AUTOMATICALLY REVERT TO "READY" IF THE FULL 48 HOURS OF STANDBY HAVE BEEN USED AND THERE IS ACTIVE LIFE REMAINING.

Instrument will automatically monitor the amount of active time and standby time that has been used which is printed on the status printout (see pg. 31). If either active or standby time is exceeded, the GEM-STAT will display appropriate message.

PROCEDURE

ACTION	RESULT
Press SHIFT and then the 1/STDBY keypad.	Alphanumeric display will read "GOING 2 STBY" for about 5 seconds. System will finish what it is doing, e.g., rinse, calibrate, etc., then the alphanumeric display will read "STANDBY" and remain in STANDBY until signaled to exit.

TO EXIT STANDBY MODE

ACTION	RESULT
Press SHIFT and the 1/STDBY keypad	Alphanumeric display will read "EXITING STBY" from 0-90 seconds, then read "RINSE 3:46." If needed, a 2 point calibration will occur.

5. INITIATING A TWO-POINT CALIBRATION

DESCRIPTION

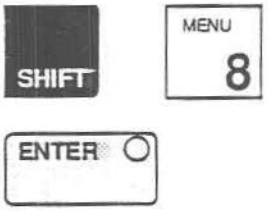
Occasionally, one of the GEM-STATPAK sensors may be slow to equilibrate following its insertion into the instrument. This is indicated by a Quality Control Check or Calibration Failure (page 21).

The "slow" sensor is usually corrected by the automatic two-point calibration which occurs 20 minutes following "WARMUP," and once per hour thereafter. The user may choose to manually initiate a calibration in order to bring the sensor to equilibration quickly instead of waiting for the next two-point calibration.

NOTE: A TWO-POINT CALIBRATION SHOULD BE INITIATED ONLY ONCE PER CARTRIDGE IF REQUIRED DURING THE QC PROCESS. IF DOING SO FAILS TO PRODUCE SATISFACTORY RESULTS, THE CARTRIDGE SHOULD BE REPLACED.

PROCEDURE

ACTION	RESULT
Press SHIFT keypad, then 8/MENU keypad	Alphanumeric display will read "2 PT. CAL." and ENTER keypad will be flashing.
Press ENTER.	2 point calibration will occur.



6. DATA RETRIEVAL

DESCRIPTION

The GEM-STAT System begins storing data as soon as a cartridge is inserted into the instrument. All of the data pertaining to that cartridge is retained until a new cartridge is inserted. The DATA RETRIEVAL function permits the user to obtain a duplicate printout of all transactions that have taken place since the cartridge has been inserted. There are two types of data retrieval:

a. Quality Control Data Retrieval

   Provides duplicate printouts of all quality control checks that have been run on the cartridge that is inserted.

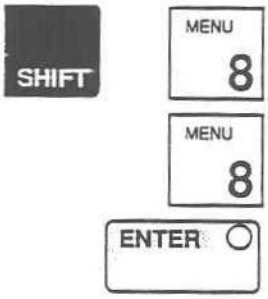
b. Total Data Retrieval

   Provides duplicate printouts of all blood analyses, status reports and quality control checks that have been run on the cartridge that is inserted.

PROCEDURE (QC DATA RETRIEVAL)

If QC has not been run, instrument will not perform this function.

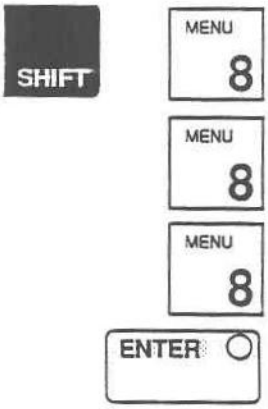
ACTION	RESULT
Press SHIFT keypad, then 8/MENU keypad.	Alphanumeric display will read "2 PT. CAL." and ENTER keypad will be flashing.
Press 8 to scroll to next selection.	Alphanumeric display will read "PRINT QC" and ENTER keypad will be flashing.
Press ENTER.	GEM-STAT will duplicate all QC checks that occurred since cartridge was inserted.



PROCEDURE (TOTAL DATA RETRIEVAL)

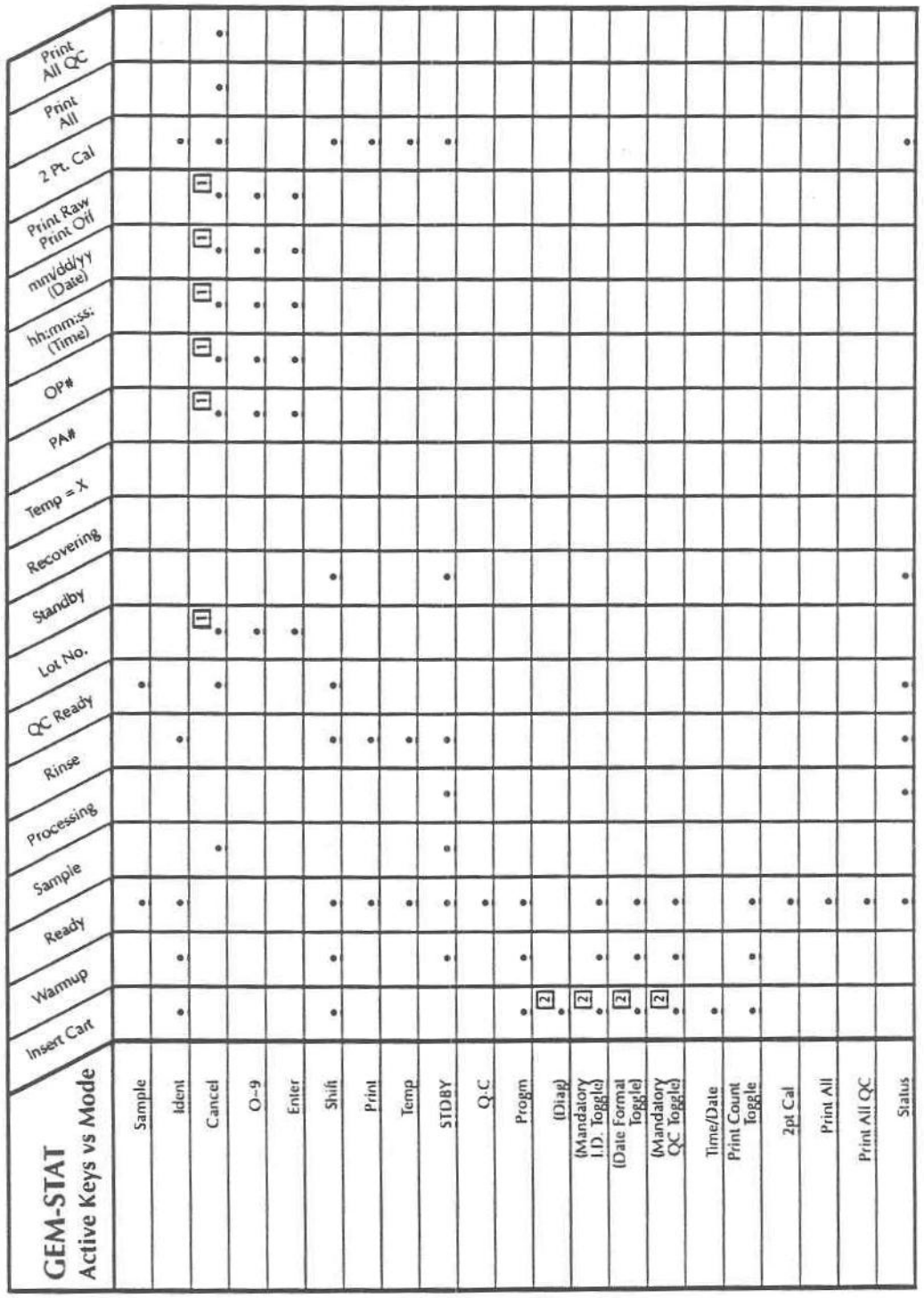
If patient samples have not been run, instrument will not perform this function.

ACTION	RESULT
Press SHIFT keypad, then 8/MENU keypad.	Alphanumeric display will read "2 PT. CAL." and ENTER keypad will be flashing.
Press 8 keypad to scroll to next selection.	Alphanumeric display will read "PRINT QC" and ENTER keypad will be flashing.
Press 8 keypad to scroll to next selection.	Alphanumeric display will read "PRINT ALL" and ENTER keypad will be flashing.
Press ENTER	GEM-STAT will duplicate all transactions that have occurred since cartridge was inserted.



7. ACTIVE KEYS VS MODE

THE FOLLOWING CHART SUMMARIZES WHICH KEY FUNCTIONS CAN BE ACCESSED DURING EACH GEM-STAT MODE.



GEM-STAT Active Keys vs Mode	Insert Cart	Warmup	Ready	Sample	Processing	Rinse	QC Ready	Lot No.	Standby	Recovering	Temp = X	PA#	OP#	hh:mm:ss: (Time)	mm/dd/yy (Date)	Print Raw Print Off	2 Pt. Cal	Print All	Print All QC
Sample			•				•											•	
Ident	•	•	•			•		[1] •				[1] •	[1] •	[1] •			•	•	
Cancel				•				•							[1] •	[1] •	•	•	
0-9								•				•	•	•	•	•			
Enter								•				•	•	•	•	•			
Shift	•	•	•			•	•		•								•		
Print			•			•											•		
Temp			•			•											•		
STDBY		•	•	•	•	•			•								•		
Q.C			•																
Progm	•	•	•																
(Diag)	[2] •																		
(Mandatory I.D. Toggle)	[2] •	•	•																
(Date Format Toggle)	[2] •	•	•																
(Mandatory QC Toggle)	[2] •	•	•																
Time/Date	•																		
Print Count Toggle	•	•	•																
2pt Cal			•																
Print All			•																
Print All QC			•																
Status			•		•	•	•		•								•		

[1] = First actuation clears display
Second actuation causes return to ready mode.

[2] = These are "hidden" functions accessed by Shift-Ident-X (See Separate List)

Fig.25

D. CARTRIDGE REMOVAL

DESCRIPTION

If the cartridge door is opened while a cartridge is inserted, the cartridge must be replaced.

The cartridge door lock keeps the cartridge door from being inadvertently opened. The cartridge door will automatically open IF the use life of the cartridge is over 50 samples or 24 hours of "active" use life. (See pg.32)

The cartridge can be removed prior to the end of its use-life by one of two procedures.

PROCEDURE

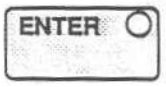
1. Disconnect the power to the instrument by turning unit OFF, or
2. The operator uses the following key sequence:

a) Press SHIFT, then immediately press 8/MENU (1 to 4 times) until "REMOVE CART?" appears on the alphanumeric display.

Alphanumeric display will read "REMOVE CART?" and ENTER keypad will be flashing

b) Press ENTER

Alphanumeric display will read "R U SURE?" and ENTER keypad will be flashing.

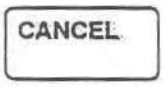


c) Press ENTER

Display will read "REMOVE CART" and door will unlock.

CARTRIDGE MUST BE REPLACED.

OR



Press CANCEL

System will return to previous mode of operation.

E. POWER INTERRUPTION AND SYSTEM TRANSPORT

GEM-STAT's small size and power interruption capability make it ideal for transport. The GEM-STAT System may be disconnected from its power source, transported, and remain completely functional, PROVIDED THAT:

1. The GEM-STATPAK is **not** removed from the instrument.
2. Power is restored within 30 minutes.

Power must be restored within 30 minutes or a new GEM-STATPAK MUST BE INSERTED.

To transport, simply disconnect from power source. When power is reconnected, display will read PLEASE WAIT, then RECOVERING. A print out will document the time of power interruption and power restoration. Following RECOVERING, a rinse and calibration may occur before system returns to READY.

Maintenance, Troubleshooting, and Service

VI

A. MAINTENANCE

1. CLEANING THE INSTRUMENT

Dampen a sponge with warm soapy water to remove blood and/or other stains from all external surfaces.

Visually inspect the GEM-STATPAK compartment to assure there has been no leakage of fluids into area.

If there is any indication of leakage in the sensor heater block located at the rear of the compartment, contact an authorized service representative before further use of the instrument. DO NOT ATTEMPT TO CLEAN THIS AREA.

WARNING

MAKE SURE THE INSTRUMENT IS TURNED "OFF" BEFORE CLEANING OR CHANGING THE FILTER.

A

Filter Cover

B

Filter

Fig. 26

2. CLEANING OR CHANGING THE FILTER

The filter (Fig. 26B) in the back of the GEM-STAT should be cleaned periodically (about once a month or whenever debris has visibly accumulated). Should a filter need replacement, refer to APPENDIX A located at the end of this manual.

NOTE: MAKE SURE THE INSTRUMENT IS OFF.

Remove the plastic cover from the filter holder located on the back of the instrument (Fig. 26A and Fig. 27).

Lift the filter from the fan and wash in a mild detergent.

Allow to dry completely before replacing filter.

Replace filter and replace plastic cover over filter, aligning the tabs on the cover with the grooves on the filter holder (Fig. 27).

Snap the cover into place.

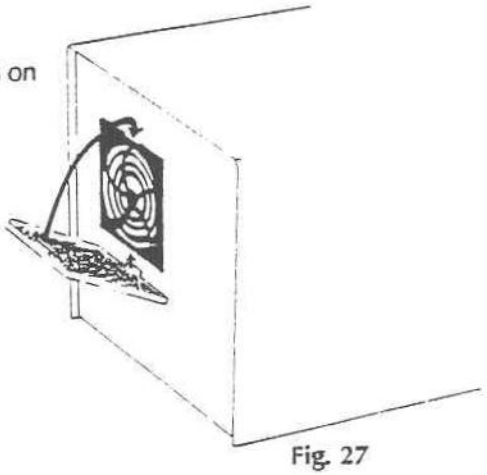


Fig. 27

B. QC TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE(S)	SOLUTION
1. PO_2 failed QC (other values are within range)	a. GEM-CHECK was not at room temperature prior to running.	a. Refer to GEM-CHECK package insert, and calculate with temperature adjustment.
	b. Wrong level is being referenced on product insert.	b. Verify that level no. shown on printout matches level no. on ampule label.
2. One or more value failed QC	a. GEM-CHECK was not at room temperature prior to running.	a. Refer to GEM-CHECK package insert, rerun at room temperature.
	b. Slow starting sensor.	b. Initiate a 2 PT. CAL or contact key operator.
	c. Cartridge problem.	c. Call customer service.
	d. Referred to wrong expected range for ampule being used.	d. Verify lot number corresponding to proper range and recheck values.
	e. The QC Ampule was "pulled away" before display changed to process, or GEM-SAMPLER was improperly inserted in ampule.	e. Refer to the QC package insert for properly aspirating the QC solution and rerun the test.
	f. QC sample was shaken vigorously, causing bubbles to be aspirated.	f. GENTLY swirl solution prior to opening. Rerun test with new solution.
3. Q.C. Values are not displayed on the instrument	This is normal. Q.C. values are never displayed (to make sure they cannot be confused with patient values.)	Refer to the Q.C. printout to obtain Q.C. test results values.

PROBLEM	POSSIBLE CAUSE(S)	SOLUTION
4. After performing a Q.C. test, the values are printed on a patient result printout rather than on a QC printout.	The Q.C. solution was aspirated more than a minute after the display read "QC READY," or SHIFT QC sequence was not followed.	Although the values on the printout are valid, the test should be redone to obtain proper documentation.
5. pH, Hct, K^+, & Ca^{++} parameters fail Q.C. while PO_2, & PCO_2 values pass Q.C.	Cartridge has an internal pumping problem.	Replace cartridge and call Customer Service.
6. Q.C. checks reveal low Hct and high K^+.	Instrument has internal pumping problem.	Call Customer Service.
7. PO_2, repeatedly reads 7 or 185.	Cartridge problem.	Replace cartridge and call Customer Service.

C. GENERAL TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE(S)	SOLUTION
1. Sample will not aspirate	a. Instrument not in "READY" mode	a. Wait until System is "READY"
	b. GEM-SAMPLER clogged	b. Change GEM SAMPLER.
	c. SAMPLER not inserted completely into cartridge	c. Push SAMPLER until "stop line" is flush with cartridge.
	d. Instrument is not pumping	d. Call customer service.
2. Cartridge is leaking:		
a. prior to inserting	a. Shipping damage	a. Replace cartridge and call customer service.
b. after insertion into instrument	b. Cartridge was installed a second time.	b. Replace cartridge

PROBLEM	POSSIBLE CAUSE(S)	SOLUTION
3. Paper is jammed	Paper has wound around roller inside the front printer door.	Grab end of cut paper and pull out. If it does not pull out easily, call customer service.
4. Printer feeds paper, but does not print	Either paper was installed upside down or non-thermal paper was inserted.	Install thermal paper as directed.
5. After date and time have been set and power has been turned off then on, date and time are incorrect.	Battery low	Call customer service.
6. Values do not compare with the lab on one cartridge.	a. Sample for lab is mishandled or there is a time delay in transporting it to the lab.	a. Correct sample technique and eliminate time lag. Call Customer Service for more information.
	b. Laboratory instrument is out of calibration.	b. Request lab to calibrate their instrument.
	c. GEM instrument is out of calibration	c. Initiate a 2-Point Calibration as described in Section V C, "Initiating a 2-Point Calibration."
	d. Cartridge problem.	d. Replace cartridge and call Customer Service.
7. Values do not compare with the lab for multiple cartridges as compared to previous cartridges.	Instrument problem	Call Customer Service.

PROBLEM	POSSIBLE CAUSE(S)	SOLUTION
8. Instrument will not go into Standby.	a. Standby time has been exceeded.	a. Use remaining active sampling time or replace the cartridge.
	b. Tried to go into Standby while the instrument was performing another task.	b. If the display momentarily shows "GOING 2 STBY," it will resume the current task and go into Standby when the task is completed. If it does not show this display, try to put it into Standby again.
DISPLAY READS:		
1. BAD DATE	Invalid date entered (Year <80 or >99)	Enter correct date
2. BAD LOT NUM	Invalid QC lot number has been entered	Enter correct lot number. (Printed on GEM-CHECK ampule).
3. BAD TIME	Invalid time has been entered	Enter correct time
4. CRC FAILED	Processor Problem	Turn power OFF, then ON. If same message appears, call customer service.
5. HEATER BLK FAIL	a. Heater block did not reach 37° prior to processing blood	1) Wait for, or force, a 2 point calibration. Re-run sample. 2) If message appears again, call Customer Service.
	b. Instrument is being operated outside of acceptable ambient temperature range.	b. Move instrument or call customer service.
6. MUST DO QC	QC analysis required prior to analysis of first blood sample	Run at least 1 QC check, then run blood analysis

DISPLAY READS:		
7. NO GOOD DATA	Data is unavailable to allow a completed calculation, eg., data retrieval is requested before any samples have been analyzed.	Enter necessary data and try again.
8. OP000000000; sample won't aspirate	Instrument asking for operator identification numbers	Enter operator ID number, press ENTER
9. PA000000000; sample won't aspirate	Instrument asking for patient identification numbers	Enter patient ID number, press ENTER
10. PLEASE WAIT	Instrument is "busy" performing other functions	Wait, display message will change momentarily.
11. RECOVERING	Power interruption has occurred.	Instrument will automatically recover and follow with a rinse and/or 2 point calibration.
12. "REMOVE CART" (remove cartridge)	a. Door has been opened	a. Cartridge must be replaced.
	b. Cartridge life is expended	b. Cartridge must be replaced.
	c. A power failure has occurred and lasted for over 30 min.	c. Cartridge must be replaced.
	d. Low battery (if none of above has happened.)	d. Call customer service.
	e. Request to Remove Cart was selected through keypad entry.	e. Cartridge must be replaced.
13. SAMPLE ERROR	a. Air was aspirated with sample	a. Rerun with fresh sample
	b. SAMPLER not inserted completely into cartridge	b. Push SAMPLER until "stop line" is flush with cartridge
14. VALVE FAILED	Internal valve failure	1. Leave cartridge inserted, RESET instrument by turning OFF, then ON. 2. Call customer service.

D. SERVICE AND RETURNED GOODS POLICY

NOTE: RETAIN ALL PACKAGING MATERIALS IN CASE THE GEM-STAT INSTRUMENT REQUIRES SERVICING.

Inspect packing case and remove instrument to examine it for external signs of damage. If damage has occurred, a claim must be filed with the delivering carrier within 10 days. Although the Mallinckrodt Sensor Systems Warranty does not cover damage due to shipping, our Customer Service Department or an Authorized Agent will assist you in determining the damages so that a proper claim may be filed.

When an agreement has been reached between the carrier and the customer, Mallinckrodt Sensor Systems will arrange the repair or replacement of the damaged goods.

If you feel service may be necessary, contact customer service. If it is decided that a component should be repaired or replaced, you will be issued a Return Goods Authorization (RGA) number.

Under no circumstances should the customer attempt to return a product without first receiving a Return Goods Authorization Number from Mallinckrodt Sensor Systems' Customer Service Department.

The Return Goods Authorization Number must be referenced on the shipment packing list and be visible on any package returned to Mallinckrodt Sensor Systems. Warranty of individual components may vary. Refer to warranty statement enclosed with each product.

Ship product to:

MALLINCKRODT SENSOR SYSTEMS
1590 EISENHOWER PLACE
ANN ARBOR, MI 48108

Phone:

(800) 262-3654

In Ann Arbor:

(313) 973-7000

Additional Information VII

A. ORDERING INFORMATION

DESCRIPTION	QTY. PER CASE	PART NO.
GEM-STAT	1	4300
GEM-STATPAK	4	4301
GEM-SAMPLER	200	4305
GEM-CHECK	3 Levels 10/ea level	2306
GEM-crit CHECK	2 levels 15/ea level	2309
Printer Paper	10 Rolls	2308
Filter	1	700038
Filter Cover	1	700039
Operators Manual	1	380019
Quality Assurance Manual	1	380023

B. SUMMARY OF CAUTIONS AND WARNINGS

THE GEM-STAT CONSISTS OF SEVERAL NON-INTERCHANGEABLE COMPONENTS. USE COMPONENTS MANUFACTURED ONLY BY MALLINCKRODT SENSOR SYSTEMS. READ THE INSTRUCTION MANUAL PROVIDED WITH EACH COMPONENT BEFORE OPERATING THIS SYSTEM.

WHILE MALLINCKRODT SENSOR SYSTEMS WARRANTS THE GEM SYSTEM TO PERFORM WITHIN THE SPECIFICATION LIMITS STATED IN THIS MANUAL, IT IS THE RESPONSIBILITY OF THE USER TO REVIEW THE SPECIFICATIONS AND DETERMINE THE SUITABILITY OF THE SYSTEM FOR ANY SPECIFIC APPLICATION.

UNDER NO CIRCUMSTANCES SHOULD THE COVER OF THIS INSTRUMENT BE REMOVED. THERE ARE NO USER SERVICEABLE PARTS IN THE INSTRUMENT.

IN ORDER TO PREVENT ELECTRICAL SHOCK HAZARD TO OPERATOR, THIS DEVICE MUST BE GROUNDED BY CONNECTING IT TO A PROPERLY WIRED RECEPTACLE.

CHECK THE EXPIRATION DATE ON THE GEM-STATPAK. DO NOT USE AFTER INDICATED EXPIRATION DATE.

IF THERE IS ANY MOISTURE INSIDE BAG OR ON CARTRIDGE, DO NOT USE CARTRIDGE. OPEN A FRESH GEM-STATPAK AND CALL CUSTOMER SERVICE.

BEFORE INSERTING GEM-STATPAK, MAKE CERTAIN THAT THE INSTRUMENT DISPLAY READS "INSERT CART."

CARTRIDGE MUST BE INSERTED INTO THE GEM-STAT WITHIN ONE MINUTE OF REMOVAL OF PROTECTIVE COVER.

ONCE INSERTED, DO NOT REMOVE GEM-STATPAK FROM GEM-STAT UNTIL END OF PROCEDURE. GEM-STATPAK IS RENDERED NON-FUNCTIONAL IF REMOVED FROM INSTRUMENT.

IF THE GEM-STATPAK HAS BEEN INSERTED PRIOR TO TRANSFERRING THE SYSTEM TO ANOTHER LOCATION, DO NOT REMOVE THE GEM-STATPAK FROM THE INSTRUMENT.

DO NOT INJECT SAMPLE DIRECTLY INTO SYSTEM VIA A SYRINGE. THIS WILL CAUSE SERIOUS DAMAGE TO BOTH THE GEM-STATPAK AND THE INSTRUMENT. USE THE GEM-SAMPLER ACCORDING TO INSTRUCTIONS.

IF AIR IS INADVERTENTLY INTRODUCED INTO SAMPLE DURING ASPIRATION, RESULTS WILL BE ERRONEOUS.

USE ONLY HEPARINIZED BLOOD.

HEMATOCRIT READINGS ARE PERFORMED USING A CONDUCTIVITY CELL METHOD WHICH IS DEPENDENT ON THE ELECTRICAL RESISTANCE OF THE PATIENTS' PLASMA REMAINING CONSTANT. CHANGES IN THIS RESISTANCE DUE TO VARIATIONS IN THE CRYSTALLOID/COLLOID BALANCE OF THE PLASMA MAY CAUSE A SHIFT IN REPORTED VALUES. A HIGHER CRYSTALLOID-TO-COLLOID RATIO WILL LOWER THE REPORTED HCT READINGS WHILE THE INVERSE WILL SHIFT THE READINGS SLIGHTLY HIGHER.

SEE PACKAGE INSERT PROVIDED WITH EACH GEM-CHECK PACKAGE AND SECTION V PRINCIPLES OF OPERATION, BEFORE ATTEMPTING TO USE THE QUALITY CONTROL SOLUTIONS.

STABILITY OF QUALITY CONTROL SOLUTION DEGRADES QUICKLY AFTER OPENING GLASS AMPULE. PROCEED WITH SAMPLE WITHIN 1 MINUTE AFTER OPENING AMPULE.

BLOOD FROM PATIENTS ANESTHETIZED WITH HALOTHANE MAY PRODUCE UNRELIABLE PO_2 READINGS DUE TO INTERFERENCE WITH PO_2 SENSOR.